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MITRAL ANNULAR REDUCTION WITH SUBABLATIVE HIGH INTENSITY FOCUSED ULTRASOUND: SAFETY, EFFICACY AND DOSE RESPONSE IN AN ANIMAL MODEL

i2 Oral Contributions
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Background: Mitral annular (MA) reduction may reduce functional mitral regurgitation (MR). We sought to evaluate the potential for MA reduction of a novel device utilizing High Intensity Focused Ultrasound (HIFU).

Methods: The ReCor device was studied in a closed chest canine model. Under fluoroscopy, a 12 Fr HIFU balloon catheter (ReCor, Inc) was advanced to the left atrium (transeptal approach), its balloon inflated with contrast-saline and positioned at the MA. HIFU energy was delivered locally at the MA with 5 sonifications. Transthoracic echocardiograms measured MA dimension at various timepoints.

Results: Of 35 dogs studied, there was 1 device related death following ventricular fibrillation after 2 sonifications. There were 2 other non device related deaths: 1 anesthesia related and 1 following a retroperitoneal hematoma. There was no significant damage to the mitral leaflets or the coronary arteries. Relative to baseline, there was a significant early reduction in MA diameter (3.28±0.43 to 3.0 ±0.42 cm;figure). A dose response was observed, with degree of MA reduction influenced by power and duration of each sonification(figure). Histology showed minor endocardial thickening close to the MA with an associated increase in elastin. Transmission electron microscopy demonstrated a decrease in diameter of individual collagen fibers in treated regions compared to controls.

Conclusion: HIFU energy application causes early MA reduction which appears durable without peri-annular damage.